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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,514	10/12/2001	Matthew D. Putnam	09531-076001	9763

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EXAMINER
MELSON, CANDICE C

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/975,514	PUTNAM, MATTHEW D.
	Examiner	Art Unit
	Candice C. Melson	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24, 28-34 is/are rejected.

7)☒ Claim(s) 25-27 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12 October 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

New corrected drawings are required in this application because the drawings originally filed are informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "longitudinal channel 133". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 19,20 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 19 recites the limitation "the second channel" in line 1. There is insufficient antecedent basis for this limitation in the claim.

2) Claim 24 recites the limitation "the opening in the intramedullary rod" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1) Claims 1-3, 7-8,14, 17,21-24, and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Border (USPN 5,935,127). Border discloses a method for treatment of a fracture in long bone which comprises "an intramedullary rod 10" which "includes a joint segment 13 separated from a diaphyseal segment 15 by a middle segment 14. A channel 16 extends between ends 13 and 15 so that rod 10 can be positioned in a bone with the aid of a conventional guide pin. A slotted shaped opening 17 extends through metallic portion 12 adjacent joint segment 13. In this embodiment, slot 17 has a width just larger than the diameter of an intended fastening screw. Those skilled in the art would appreciate that other suitable fasteners could be substituted for the described screw (s)" (column 2, lines 29-41). "In order to attach the diaphyseal segment of the rod 10 it includes a pair of fastener bores 22". In addition, "although rod 10 is shown in FIG. 1 as not having a bow, those skilled in the art would appreciate that bowed rods could be used to better fit the internal contours of any suitable long bone within which rod 10 is being positioned". With respect to Claim 3, "a portion of channel 16 adjacent joint segment 13 is

threaded in order to facilitate the attachment of tools during the implantation procedure" (column 2, lines 49-52). Figure 4 shows a generally round or oval cross section of the entire intramedullary rod. Claim 17 is limiting an element that is not positively claimed therefore, the structure of the tine is not given patentable weight and the art is applied accordingly. With respect to Claim 14, Border discloses "guide 30" which "is attached to the internal threads 20 of the proximal end of the rod 10 and mated to notches 18 as shown in FIG. 2" (column 3, lines 12-14). Because a drilling guide is disclosed there is inherently a drill bit. Furthermore, in anticipation of Claims 31 and 32, the tensioning device is not positively claimed therefore there is no patentable weight given to the structure.

2) Claims 1-3, 7-8, 14-24 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Moehring (USPN 4,846,162). Moehring discloses a method for bone fracture fixation including a "rod 10" which is "dimensioned to substantially conform to the shape of the medullary canal of bone". "A first transverse aperture 20 extends through opposing wall portions of rod 10 at a second, opposite end 13 thereof spaced a first predetermined longitudinal distance X from a second end 13 of the rod. An optional second transverse aperture 22 extends through opposing wall portions of rod 10 spaced a second predetermined longitudinal distance Y from bight portion 16" (column 3, lines 25-32). The second end is the joint segment and the bight portion is the diaphyseal segment. With respect to Claims 3, 18-19 and 23, "channel 26 is threaded for the outermost several centimeters at the joint segment. With respect to Claims 7 and 8, figure 3 shows a generally round cross-section of the intramedullary rod. Furthermore, "a guide pin 40" is disclosed. Figure 4 shows that the guide pin is inserted and mounted to the first mounting section at the diaphyseal segment. In anticipation of Claim 16, "a guide 52 is attached

to second end 13 of rod 10 by a threaded shaft 58 that extends through a hollow body 54 and threadably engages the threads on inner wall surface 26 (FIG. 5)" (column 4, lines 42-46). The limitations as stated in Claim 17 are also met because applicant is limiting an element that is not positively claimed therefore, the structure of the tine is given no patentable weight. "A drill bit 64" is disclosed in anticipation of Claim 30. Lastly, with respect to Claims 31 and 32, the tensioning device is not positively claimed therefore the structure is given no patentable weight.

3) Claims 1-3, 7-8, 14-15,17-24 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Durham et al. (USPN 6,106,528). Durham et al. disclose a modular intramedullary fixation system which "intramedullary rod 13". "The intramedullary rod 13 includes an elongated body 15 consisting, in general, of a hollow shaft, and having a joint segment 17 and a diaphyseal segment 19. Joining these two segments is a middle segment. The joint segment 17 of the body 15 of the intramedullary rod 13 has a transverse aperture therethrough" (column 8, lines 35-39). "As indicated above, the body 15 preferably consists of a hollow shaft and the channel 25 preferably extends completely through the body 15, from the joint segment 17 to the diaphyseal segment 19 thereof as will now be now more apparent to those skilled in the art" (column 8, lines 43-47). Durham et al also show "channel 25" having a "threaded portion 39". Figure 4 shows a generally round cross-section of the rod. Figure 2 shows that the rod has a curved configuration similar to the curvature of the intramedullary canal. Claims 14 and 15 are anticipated by "guide 301" which is used "to orient drill guides 389". Because there a drill guide 301 disclosed by Durham et al, inherently there is also a drill bit, thus anticipating Claim 30. With respect to Claim 17, it is further disclosed that "a pair of joint segment bone screws S are inserted horizontally through the lateral bone cortex of the

femur F, through the aperture 21" (column 18, lines 41-43). Figures 39 and 41 show the screws S. The screw S is considered to be a tine. Finally with regards to Claims 31 and 32, the tensioning device is not positively claimed and therefore the structure is given no patentable weight.

4) Claims 1, 4-8, and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Cole et al. (USPN 6,221,074). Cole et al. disclose an "intramedullary kit 10". "Although kit 10 is shown implanted in a human femur 12, kit 10 could also be used in conjunction with other bones as would occur to one skilled in the art, including but not limited to, the tibia, humerus, radius, ulna, and fibula. Rod 14 includes a joint segment 14a and a diaphyseal segment 14b. Rod 14 defines a longitudinal centerline axis L1 running along the length of the rod 14 between joint segment 14a and diaphyseal segment 14b. For application to an adult femur, joint segment 14a preferably has a diameter of about 11-13 millimeters. The diameter of the remainder of rod 14 may vary depending upon the requirements of the fixation procedure and the surgeon's preference. While rod 14 has a generally circular cross-section, other suitable shapes are also contemplated as would occur to one skilled in the art. Furthermore, with respect to Claims 11-13, figure 1 shows the first mounting section channels 24a and 24b are threaded and receive bone screws 22a and 22b, respectively. Both screws shown are bicortical bone screws.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 4-6, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border in view of Matthews (USPN 5,779,705). Border discloses an intramedullary rod kit as disclosed in Claims 1-3 and 7-8. Matthews discloses "a surgical intramedullary rod". "Typically, the rods may be manufactured in varying lengths and diameters from a biologically inert material which is sterilized and has appropriate mechanical strength. The section of the nail is typically tubular with an outer diameter of approximately 12 to 16 mm" (column 3, lines 35-41). It would have been obvious to one of ordinary skill at the time of the invention to incorporate the variable lengths and diameters and as taught by Matthews into the kit disclosed by Border in order to provide the appropriate dimensions for easier, more secure insertion in the bone.

2) Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border in view of Allen et al. (USPN 5,979,658). Border discloses the claimed invention except for written instructional information and an instructional video. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include written instructions and an instructional video into any kit since it was known in the surgical art that physicians and/or patients might require training on use of products. For example, in the kit disclosed by Allen et al., an instructional video and written instructions are provided.

3) Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Border in view of Cachia et al. (US 2001/0049529). Border discloses an intramedullary rod kit as stated in Claim 1 however, they do not disclose a kit where the diaphyseal surface of the rod comprises dimples and there is a therapeutic coating either on the rod, tensioning device or tine. In a similar art, Cachia et al. disclose a bone fixation device with an elongated body where a "micropitted or otherwise textured surface" is provided "on the anchor components" (paragraph 0094). Furthermore, Cachia et al disclose "the anchor components of the invention may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like" (paragraph 0093). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a textured surface and bioactive coating, as taught by Cachia et al. to the intramedullary rod disclosed by Border in order to enhance osteoincorporation and to contribute to the healing of the injury in addition to providing mechanical support, respectively.

Allowable Subject Matter

Claims 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

ccm
November 22, 2002

Cary E. O'Connor
Primary Examiner